REMARKS

Introductory Comments:

In the Office Action under reply, the claims were subjected to a restriction requirement under 35 U.S.C. §121. The claims were classified in four groups:

Group I: drawn to a modular microchannel apparatus (claims 1-12 and 25);
Group II: drawn to a modular microchannel apparatus (claim 13);
Group III: drawn to a method of making a modular microchannel apparatus (claims 14-21); and
Group IV: drawn to a method of using a modular microchannel apparatus (claims 22-24).

A provisional election of the claims of Group I was made with traverse in a telephone conversation on December 7, 1999. As a result of this election, only claims 1-12 and 25 were examined in the Office Action mailed December 20, 1999. In the Office Action, the examined claims were rejected, as follows:

1. under 35 U.S.C. §112, second paragraph, as indefinite (claims 5 and 10-12);
2. under 35 U.S.C. §103(a) as obvious over Swedberg et al. (claims 1-4, 6-7 and 25);
3. under 35 U.S.C. §103(a) as obvious over Swedberg et al. in view of Kambara et al. (claims 5 and 8-9); and
4. under 35 U.S.C. §103(a) as obvious over Swedberg et al. in view of Kaltenbach et al. (claims 10-12).

The drawings were also objected to as failing to show **Figure 7** as described in the specification and as failing to include reference **106a**.

Claims 1-14, 16-21 and 25 have been amended to correct minor grammatical errors. Claim 15 has been canceled and new claims 26 and 27 have been added. Thus, claims 1-14, 16-21 and 25-27 are now pending.

The Above Amendments:

The specification has been amended to clarify that the drawing referred to on page 10 of the specification, line 14, is **Figure 7a.**

Claims 1-14, 16-21 and 25 have amended to correct minor grammatical errors.

Claims 1, 3, 5, 8, 13, 14, 17, 19 and 25 have also been amended to specify that the reservoir unit supplies liquid reagents and analyte to the separation unit. Support for these amendments is found on page 6, lines 20- 22; page 7, line 4; page 9, lines 2-3 and lines 14-15.

Claims 8 and 9 have been amended to clarify that the electrical communication is an electrical connection. Support for these amendmentss is found on page 12, lines 8-10.

Claims 10, 13 and 20 have been further amended to clarify that the peltier plate is operatively and modularly coupled to a support plate. Support for these amendments is found on page 7, lines 22-24. Claim 10 has also been amended to correct its dependency to new claim 26.

Claims 12 and 21 have also been amended to clarify that the heat exchanger transfers heat between the peltier plate and the surrounding environment. Support for these amendments is found on page 13, line 7.

Claim 14 has been amended to incorporate the elements of claim 15. Claim 15 has, accordingly been canceled. This cancellation is without prejudice, without intent to acquiesce in any rejection of record and without intent to abandon any previously claimed subject matter.

Claim 16 has been amended so that it is parallel in scope to analogous apparatus claim 2.

Claim 19 has been amended to clarify that a powering plated having a probe therein is coupled to the reservoir unit so that the probe is inserted into at least one of the reservoirs. Support for this amendment is found on page 12, lines 3-6.

Claim 20 has been amended to correct its dependency to new claim 27.

New claims 26 and 27 have been added to specify that a support plate is coupled to the separation unit. Support for these new claims is found on page 7, lines 12-16.

As the amendments are supported by the original disclosure, no new matter has been added.

The New Claims:

New claims 26 and 27 have been added. New claim 26 specifies that the apparatus is to additionally comprise a support plate operatively and modularly coupled to the separation unit.

New claim 27 provides the additional step of operatively and modularly coupling a support plate to the separation unit. Support for the new claims is found on page 7, line 12.

The Pending Claims:

For the Examiner's convenience in reviewing this communication and reconsidering the application, the following is applicants' tabulation of the pending claims after entry of the above amendments:

1. A modular microchannel apparatus for analysis of an analyte, comprising:

(a) a separation unit having a microchannel, in which the analyte can be driven to pass through the microchannel due to the molecular characteristics thereof and wherein the time for the analyte to pass through the microchannel is indicative of the molecular characteristics of the analyte; and

(b) a reservoir unit having one or more reservoirs having dimensions compatible with the separation unit for operatively and modularly coupled to the separation unit to supply liquid reagents and analyte thereto, the reservoir having prepackaged liquid reagents therein before the reservoir unit is coupled with the separation unit.

2. An apparatus according to claim 1, wherein the separation unit is chip-shaped and formed from a first half and a second half each having a substantially planar surface facing and joining the other half, wherein at least one of the planar surfaces has a channel thereon such the joining of the two surfaces forms the microchannel.

3. An apparatus according to claim 1, wherein the separation unit has one or more openings leading to the microchannel capable of admitting liquid reagents such that when the separation unit and the reservoir unite are operatively and modularly coupled, the openings are aligned with the reservoirs thereby allowing the liquid reagents and the analyte to pass from the reservoirs into the microchannel without substantial leakage.

4. An apparatus according to claim 2, wherein the separation unit includes a substrate comprised of a material other than silicon or silicon dioxide in which the microchannel is formed by laser ablation.

5. An apparatus according to claim 2, wherein the reservoir unit includes a membrane that covers at least one of the reservoirs confining the prepackaged liquid reagent therein, wherein the membrane is penetrable with a probe for applying a driving force to drive movement of liquid reagent and analyte from the reservoir through the microchannel.

6. An apparatus according to claim 2, wherein both substantially planar surfaces have a laser-ablated channel thereon and the two channels join to form the microchannel.

7. An apparatus according to claim 2, wherein the channel is formed by laser ablation.

8. An apparatus according to claim 2, further comprising a powering plate operatively and modularly coupled to the reservoir unit, the powering plate having an electrical connection to at least one of the reservoirs to provide a driving force to drive movement of the liquid reagents and analyte from the reservoir through the microchannel.

9. An apparatus according to claim 8, wherein the powering plate comprises probes for inserting into at least one of the reservoirs to provide the electrical connection thereto.

10. An apparatus according to claim 26, further comprising a peltier plate operatively and modularly coupled to the support plate for controlling the temperature of the separation unit.

11. An apparatus according of claim 10, wherein the peltier plate can be used to heat or cool the separation unit by selecting an appropriate mode of operation.

12. An apparatus according to claim 11, further comprising a heat exchanger operatively connected to the peltier plate to transfer heat between the peltier plate and the surrounding environment.

13. A modular microchannel apparatus for analysis of an analyte, comprising:

(a) a separation unit having a microchannel, in which the analyte can be driven to pass through the microchannel due to the molecular characteristics thereof, the separation unit being chip-shaped and formed from a first half and a second half, each having a substantially planar surface facing and joining the other half, wherein at least one of the substantially planar surfaces has a channel laser ablated thereon such that joining of the two surfaces forms the microchannel , and further wherein the time for the analyte to pass through the microchannel is indicative of the molecular characteristics of the analyte and the separation unit has one or more openings leading to the microchannel capable of admitting liquid reagents and analyte; and

(b) a reservoir unit having one or more reservoirs having dimensions compatible with the separation unit operatively and modularly coupled to the separation unit to supply liquid reagents and analyte thereto, such that when the separation unit and the reservoir unit are operatively and modularly coupled the openings are aligned with the reservoirs thereby allowing the liquid reagents and analyte to pass from the reservoirs into the microchannel without substantial leakage, the reservoir having prepackaged liquid reagents therein before the reservoir unit is coupled to the separation unit, wherein the reservoir unit includes a membrane covering at least one of the reservoirs containing the prepackaged liquid reagent therein, the membrane is penetrable with a probe for applying a driving force to drive movement of the liquid reagent and analyte from the reservoir through the microchannel when the separation unit and the reservoir unit are operatively and modularly coupled together;

(c) a powering plate operatively and modularly coupled to the reservoir unit, the powering plate having probes for inserting into at least one of the reservoirs to provide a driving force to drive movement of the liquid reagents and analyte from the reservoir through the microchannel;

(d) a support plate operatively and modularly coupled to the separation unit; and

(e) a peltier plate operatively and modularly coupled to the support plate for controlling the temperature of the separation unit.

14. A method for making a modular microchannel apparatus for analyzing an analyte, comprising the steps of:

(a) providing a separation unit having a microchannel in which the analyte can be driven to pass through the microchannel due to the molecular characteristics thereof and wherein the time for the analyte to pass through the microchannel is indicative of the molecular characteristics of the analyte; and

(b) operatively coupling to the separation unit a reservoir unit containing one or more reservoirs capable of supplying liquid reagents and analyte to the separation unit, the reservoirs having prepackaged liquid reagents therein before the reservoir unit is coupled to the separation unit.

16. The method of claim 14, wherein the separation unit is chip-shaped and formed from a first half and a second half, each half having a substantially planar surface facing and joining the substantially planar surface of the other half, wherein at least one of the substantially planar surfaces has a channel laser ablated thereon such that joining of the two surfaces forms the microchannel.

17. The method of claim 14, wherein the separation unit has one or more openings leading to the microchannel capable of admitting the liquid reagents and analyte such that when the separation unit and the reservoir unit are operatively and modularly coupled, the openings are aligned with the reservoirs, thereby allowing the liquid reagents and analyte to pass from the reservoirs into the microchannel without substantial leakage.

18. The method of claim 14, wherein the separation unit includes a substrate comprised of a material other than silicon or silicon dioxide in which the microchannel is formed by laser ablation.

19. The method of claim 14, further comprising step (c) operatively and modularly coupling a powering plate having a probe therein to the reservoir unit so that the probe is inserted into at least one of the reservoirs to provide a driving force to drive movement of the liquid reagents and analyte from the reservoir through the microchannel.

20. The method of claim 27, further comprising step (e) operatively and modularly coupling a peltier plate to the support plate to heat or cool the separation unit by selecting an appropriate mode of operation.

21. The method of claim 20, further comprising step (f) operatively and modularly coupling a heat exchanger to the peltier plate to transfer heat between the peltier plate and the surrounding environment.

25. A kit for making a microchannel apparatus for analysis of an analyte, comprising:

(a) a separation unit having a microchannel, in which the analyte can be driven to pass through the microchannel due to the molecular characteristics thereof and wherein the time for the analyte to pass through the microchannel is indicative of the molecular characteristics of the analyte; and

(b) a reservoir unit having one or more reservoirs having dimensions compatible with the separation unit for coupling operatively and modularly to the separation unit to supply liquid reagents and analyte thereto, the reservoirs having prepackaged liquid reagents therein.

26. The apparatus according to claim 9, further comprising a support plate operatively and modularly coupled to the separation unit.

27. The method of claim 19, further comprising step (d) operatively and modularly coupling a support plate to the separation unit.

The Restriction Requirement:

Applicant elects the subject matter of Group (I) with traverse on the ground that the claims of Groups (I) and (II) could easily and properly be examined together as could the claims of Groups (I) and (III).

The Examiner has stated that the inventions of Groups (I) and (II) are related as combination (claim 13) and subcombination (claims 1-12 and 25). That is, claim 1, the independent claim of Group (I), recites a modular microchannel apparatus comprised of a separation unit and a reservoir unit while claim 13 recites a modular microchannel apparatus which is essentially the identical apparatus of claim 1 but with the elements of the various Group (I) dependent claims incorporated therein.

Restriction in such a case is addressed in Section 806.05(c) of the Manual of Patent Examining Procedure which requires two-way distinctness, i.e., it must be shown that the combination does not require the particulars of the subcombination as claimed for patentability, and that the subcombination can have utility by itself or in other contexts. Applicant submits that in the present case this test is not met.

The Examiner has stated that the combination does not require the "particulars" of the apparatus of claim 1 for patentability as the powering plate and peltier plate are not necessary for the combination apparatus to perform as a modular microchannel for the analysis of an analyte. Applicant points out that the subcombination elements are the separation unit and the reservoir unit rather than the power and peltier plates. The power and peltier plates are found in the dependent claims of Group I and not in independent claim 1. Removal of the subcombinational elements, i.e., the separation unit and the reservoir unit, leave claim 13 with only a powering plate, a support plate and a peltier plate, a combination which has no stated utility. Thus, this first part of the test, that the combination not require the particulars of the subcombination for patentability, is not met, and restriction is improper.

Applicant also points out that as the claims are so closely related, examining the two groups together should be a relatively straightforward matter. There would be no serious burden on the Office should Groups (I) and (II) be kept together. The Examiner is referred to Section 803 of the M.P.E.P., where it is stated the "[i]f the search and examination of an entire application can be made without serious burden, then the examiner **must** examine it on the merits...." This is true even though an application may include claims to distinct or independent inventions. For the foregoing reasons, it is respectfully requested that claims 1-12 and 25 and claim 13 be combined into a single group and be examined together.

As to the restriction between Groups (I) and Group (III), the groups are related as process of making (claims 14-21) and product made (claims 1-12 and 25). The relevant section of the M.P.E.P. in this instance is Section 806.05(f), which states that a process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown:

1. that the process **as claimed** ~~is not an obvious process of making~~ the product and the process **as claimed** can be used to make other and different product, or

2. that the product **as claimed** can be made by another and materially different process.

In this instance neither part of the test is met and restriction is thus improper.

Therefore, the first part of the test requires that the process as claimed is not an obvious process of making the product. In this instance the elements of the independent product claim of Group (I), claim 1, are identical in scope to the component elements of the independent process claim, claim 14. The process of claim 14 is the obvious "coupling" of the "coupled" elements of the product claim. Therefore, the first part of the test is not met.

The second part of the test requires that the product as claimed can be made by another materially different process. This test fails as well. The elements of the product claim are the exact components used in the process claim combined exactly as described in the process claim, i.e., **the identiacal separation unit and reservoir unit that are operatively and modularly coupled in the product claim are operatively and modularly coupled in the process claim.** There is no other way to make a product that contains elements that are "operatively and

modularly coupling" other than "operatively and modularly coupling" these elements. Thus, the product as claimed can not be made by another and materially different process, the second part of the test is not met and restriction is improper.

The Objection to the Drawings:

The Examiner has objected to the drawings as (1) they fail to show **Figure 7** as described in the specification and (2) do not include reservoir **106a**. In regard to the first matter, the specification has been amended to correct the typographical error on page 10, line 14, that incorrectly referred to **Figure 7a** as **Figure 7**. In regard to the second matter, **reservoir 106a** can be found on the right hand side of reservoir unit, **104,** in **Figure 1** and on the left hand side of reservoir unit, **104,** in **Figure 7a**. Reconsideration and withdrawal of the objection is accordingly requested.

The Rejection Under 35 U.S.C. §112 Second Paragraph:

The Examiner has rejected claims 1-42 as indefinite for the following reasons:

1. Claim 5 as containing a misspelled word;
2. Claim 10 as vague and indefinite as to what "operatively modularly operatively coupling" means; and
3. Claim 12 as unclear as to what is meant by "the surrounding".

These grounds of rejection have all been addressed by way of amendment, as follows.

Claim 5 has been amended to correct the misspelling error cited by the Examiner.

Claim 10 has been to clarify that the peltier plate is operatively and modularly coupled to the support plate.

Claim 12 has been amended to clarify that the heat exchanger transfers heat between the peltier plate and the surrounding environment.

As all of the grounds of rejection under §112, second paragraph, have been addressed by the above amendments, reconsideration and withdrawal of the rejection is requested.

The Rejection Under 35 U.S.C. §103(a) Over Swedberg et al.:

Claims 1-4, 6-7 and 25 have been rejected as obvious over Swedberg et al. The Examiner has cited Swedberg et al. as disclosing a separation unit including a microchannel and a reservoir unit for coupling operatively and modularly with the separation unit to supply liquid reagents thereto, specifically citing column 29, lines 47-56 of the reference. The Examiner further stated that **Swedberg et al. does not explicitly state that the reservoirs have prepackaged liquid reagents therein before the reservoir unit is coupled to the separation unit.** The Examiner asserts that it would have been obvious to one skilled in the art at the time of the invention to have included in the apparatus of Swedberg et al. prepackaged liquid reagents, in order to ensure that the reagents avoid contamination before introduction into the microchannel. Applicant respectfully disagrees.

An amended, independent claim 1 is drawn toward a modular microchannel apparatus for analysis of an analyte, comprising a separation unit and a reservoir unit having one or more reservoirs having prepackaged liquid reagents therein before the reservoir unit is coupled with the separation unit. As acknowledged by the Examiner, Swedberg et al. contains no teaching or suggestion of the inclusion of prepackaged liquid reagents into the reservoirs before the reservoir unit is coupled to the separation unit.

The section of the reference cited by the Examiner describes optional functions of the fifth access port **230**. The fifth access port may be attached to an external or "on device" fluid reservoir compartment, thereby providing a means to regulate sample flow rates through the μ-TAS or a means to introduce a reagent into fifth sample flow component **210** which reacts with the sample to facilitate sample detection by the fourth detection means **240**. Thus, the reference discloses an "on device" , e.g., on the separation unit, fluid reservoir and an "external" reservoir but **does not teach or suggest a reservoir unit that is modularly and operatively coupled to the separation unit**. Also, the reference only discloses the use of a reservoir to regulate sample flow rates and to introduce a single reagent that reacts with the sample to facilitate sample detection. **It does not teach or suggest a reservoir unit that contains prepackaged liquid regents and provides both liquid reagents and analyte to the separation unit.** The entire

focus of Swedberg et al. is on a separation unit and not on a modular apparatus comprising a separation unit and a reservoir unit.

To establish *prima facie* obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine reference teachings. Second, there must be a reasonable expectation of success and third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In this instance, the three criteria have not been met.

While the Examiner has implied that the desire to avoid reagent contamination provides the motivation to modify Swedberg et al. to include prepackaged liquid reagents, the Examiner has provided no support for the suggestion or motivation to modify Swedberg et al. to provide the modularly and operatively coupled reservoir unit of claim 1. **The section of the reference cited by the Examiner discusses possible uses of an access port and not a modularly connected reservoir unit, let alone a modularly connected reservoir unit having prepackaged liquid reagents therein.**

The first criteria has not been met and the third criteria also fails as the reference does not disclose each and every element of the claim. The modularly coupled reservoir unit of claim 1 is not disclosed. For the above reasons, *prima facie* obviousness has not been established and the rejection is in error. As claims 2-4, 6-7 and 25 all depend from claim 1, they too are nonobvious over Swedberg et al. Reconsideration and withdrawal of the rejection is requested.

The Rejection Under 35 U.S.C. §103(a) Over Swedberg et al. in view of Kambara et al.:

Claims 5 and 8-9 have been rejected as obvious over Swedberg et al. in view of Kambara et al. The Examiner has cited Swedberg et al. as before and cited Kambara et al. as teaching a reservoir unit containing a liquid and being penetrable with probes used for applying a force to

drive chemicals from the reservoir through the microchannel, specifically citing column 8, lines 4-40, of the reference. **The Examiner has acknowledged that neither reference teaches the use of a probe-penetrable membrane covering the reservoirs confining the prepackaged liquid reagent therein** but has asserted that such a modification of the references would have been obvious to one skilled in the art in order to ensure that the reagents would avoid diffusion into the microchannel prior to introduction of the probes.

As before, applicant respectfully disagrees. The rejected claims all depend from independent claim 1 which, as discussed above, is nonobvious over Swedberg et al. as Swedberg et al. does not teach the modularly and operatively coupled reservoir unit of the claim. The addition of Kambara et al. does not provide any further teaching or suggestion of such a reservoir unit and therefore provides no additional basis for the rejection of the independent claim.

Furthermore, the membrane recited in rejected claim 5 is designed to confine the prepackaged liquid reagents in the reservoir unit prior to modular coupling of the powering plate to the reservoir unit. **As neither reference contains any mention of prepackaged liquid reagents, there is clearly no teaching or suggestion of the confinement of such reagents using a membrane.**

Also, Kambara et al. has been cited for teaching a reservoir unit containing a liquid that is penetrable with probes that can supply a force to drive a chemical into a microchannel. Contrary to the Examiner's interpretation, Kambara et al. contains no teaching or suggestion of a microchannel or of the application of a force to drive chemicals from a reservoir unit into such a microchannel. Kambara et al. discloses a group of electrodes supported by an electrode holder that are used to drive chemicals through an electrophoresis separation capillary. There is no teaching or discussion of a modularly and operably coupled power plate, no teaching or suggestion of a microchannel and no teaching or suggestion that such a power plate could be used in conjunction with a microchannel.

(3)

As before, there is no suggestion or motivation to modify the teaching of Swedberg et al. and Kambara et al. to provide the reservoir unit, the prepackaged liquid reagents or

the containing membrane of the rejected claims. The references in combination fail to disclose each and every element of the claims and are an improper basis for a §103(a) rejection. Reconsideration and withdrawal of the rejection is requested.

The Rejection Under 35 U.S.C. §103(a)Over Swedberg et al. in view of Kaltenbach et al.:

Claims 10-12 were rejected as obvious over Swedberg et al. in view of Kaltenbach et al., the Examiner citing Swedberg et al. as before and stating that the peltier plate recited in these claims would have been obvious to one skilled in the art given the teaching of the reference. As before, applicant disagrees. The rejected claims depend from independent claim 1 which is nonobvious over Swedberg et al. as Swedberg et al. does not teach the modularly and operatively coupled reservoir unit recited. **The addition of Kaltenbach et al. does not provide any further teaching or suggestion of such a reservoir unit and therefore provides no additional basis for the rejection of the independent claim.** As the rejected claims all depend from a non-obvious claim, they too are nonobvious. Reconsideration and withdrawal of the rejection is thus requested.

CONCLUSION

For all of the above reasons, it is submitted that the claims now pending define an invention that is patentable over the art. As the application should now be in condition for allowance, a prompt indication to that effect would be appreciated. Should the Examiner have any questions concerning this communication, he is welcome to contact the undersigned attorney at (650)851-8501.

Respectfully submitted,

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